

Policy Clarification for Long Lasting Reversible Contraceptives and 340B Pricing

Long Acting Reversible Contraception

Long acting reversible contraception's (LARCs) are highly effective methods of contraception and have the highest continuation and satisfaction rates. LARCs can be used by most women, and increased use may reduce unintended pregnancy rates.

Operational Guidance

Effective January 1, 2016, HHSC implemented Medicaid benefit changes in an effort to increase access to and utilization of LARCs in Texas Medicaid. Medicaid managed care organizations (MCOs) are also required to implement the necessary changes to reimburse hospitals and FQHCs appropriately for providing Medicaid covered LARC devices in the same amount, duration, and scope as the Medicaid benefit requires.

Certain LARCs May Be Covered Under the 340B Drug Pricing Program

HHSC offers the following clarification applicable to any 340B Covered Entity:

340B Drug Pricing Program

The 340B Drug Pricing Program is administered by the Health Resources and Services Administration (HRSA) and allows entities covered under the program access to outpatient drugs at reduced prices. Participating covered entities (which can include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers) and drug manufacturers are responsible for compliance with all HRSA 340B requirements.

Duplicate Discounts

42 USC 256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Texas Medicaid must ensure that such duplicate discounting does not occur; however, it is the responsibility of the covered entity to correctly submit claims filled with 340B stock for 340B-eligible patients to ensure rebates are not collected for these drugs.

LARC Coverage by 340B Covered Entities Participating in Texas Medicaid

A 340B Covered Entity is responsible for ensuring that any drug or device provided to a Medicaid recipient is compliant with all applicable HRSA requirements. To the extent that a 340B Covered Entity determines that a 340B-purchased LARC may appropriately be provided on an outpatient basis to a patient found eligible by the covered entity in accordance with HRSA's rules, and further indicates to Texas Medicaid that a 340B-purchased LARC is being used for that purpose, Texas Medicaid will reimburse the covered entity for the claim and duplicate discounting will be prevented.

A 340B Covered Entity is not required under Texas Medicaid to provide a 340B-purchased LARC under any conditions which would be in violation of 340B Drug Pricing Program Rule or statute. A Covered Entity may also bill non-340B purchased LARCs on an outpatient basis to the extent that this does not violate any applicable HRSA rules or statutes.

The intent of these rules is to ensure that additional reimbursement is made available to 340B Covered Entity for the provision of LARCs. Texas Medicaid defers to the 340B Covered Entities to determine if a patient, setting and drug/device are eligible under the 340B Drug Pricing Program. Texas Medicaid only requires that if a 340B LARC is provided on an outpatient basis that the claim requirements provided below are following to ensure that duplicate discounting does not occur.

Prevention of Duplicate Discounts

HHSC requires pharmacies of eligible entities participating in the 340B Drug Pricing Program to identify all outpatient pharmacy claims filled with 340B stock for 340B-eligible patients by submitting a value of “20” (defined as “340B / Disproportionate Share Pricing/Public Health Service”) in the “Submission Clarification Code” claims submission field (420-DK). For 340B clinician-administered claims, providers must use modifier “U8.” These requirements apply to submission of claims for LARC devices purchased through the 340B Drug Pricing Program in managed care.

Additional Information

Hospital Reimbursement for Immediate Postpartum LARC

Effective January 1, 2016, hospitals may choose to bill for the following procedure codes in addition to the hospital diagnosis related group (DRG) payment if a LARC device is inserted immediately postpartum:

- J7300
- J7301
- J7302
- J7307

NOTE: For claims submitted to the Texas Medicaid and Healthcare Partnership (TMHP) for processing, hospital providers will be required to submit an outpatient claim with the appropriate procedure code for the LARC device in addition to the inpatient claim for the delivery services.

Medicaid MCOs must adopt claim processing procedures to implement add-on hospital reimbursement for immediate postpartum LARC devices.

Federally Qualified Health Center (FQHC) Reimbursement for LARC

Effective January 1, 2016, FQHCs may receive reimbursement for the following procedure codes in addition to the FQHC encounter payment:

- J7300
- J7301
- J7302
- J7307

NOTE: For claims submitted to TMHP for processing, the FQHC provider will be required to submit a claim with the appropriate procedure codes for both the family planning services provided and for the LARC device, which will no longer be subject to FQHC limitations.

Medicaid MCOs must adopt claim processing procedures to implement add-on FQHC reimbursement for LARC devices.

Pharmacy Payment for LARCs

Providers can prescribe and obtain long-acting reversible contraception (LARC) products that are on the Medicaid and Healthy Texas Women (HTW) Program drug formularies from certain specialty pharmacies for women participating in Medicaid and HTW. LARC products are only available through a limited number of specialty pharmacies that work with LARC manufacturers.

Providers who prescribe and obtain LARC products through the specialty pharmacies listed will be able to return unused and unopened LARC products to the manufacturer's third-party processor.

The following products are currently available through the pharmacy benefit:

- Mirena® (NDC **50419042101**)
- Mirena® (NDC **50419042301**)
- Skyla® (NDC **50419042201**)
- Nexplanon® (NDC **0052433001**)
- Paragard® (NDC **51285020401**)

Providers may also continue to obtain LARC products through the existing buy-and-bill process. Additional information regarding this pharmacy benefit can be found at the Vendor Drug Program website at the following link: <http://www.txvendordrug.com/formulary/larc.shtml>